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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/763,397 02/16/01 LAL

A 6395-57049

024197  
KLARQUIST SPARKMAN, LLP  
121 SW SALMON STREET  
SUITE 1600  
PORTLAND OR 97204

HM12/1009

EXAMINER

FORD, V	ART UNIT	PAPER NUMBER
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1645  
DATE MAILED:

10/09/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/763,397	LAL ET AL.
	Examiner Vanessa L. Ford	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 February 2001.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: \_\_\_\_\_.

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

**Election/Restrictions**

- Group I      Claims 1-6 and 10 are drawn to a recombinant protein comprising peptides from two or more stages in a life cycle of *Plasmodium falciparum*, wherein each peptide comprises an antigenic epitope.
- Group II     Claims 7-8 are drawn to an isolated nucleic acid molecule encoding the protein of claim 1.
- Group III    Claim 9 is drawn to a method of enhancing an immune response of an animal to *Plasmodium falciparum* comprising administration to the animal an effective amount of a protein composition comprising the recombinant protein of claim 1 and a pharmaceutically acceptable carrier.
- Group IV    Claim 11 is drawn to antibodies that are immunoreactive to the recombinant protein of claim 1.
- Group V     Claim 12 is drawn to a method of using the antibodies for simultaneous detection or measurement of peptides derived from two or more stages in a lifecycle of *Plasmodium falciparum*.

Art Unit: 1645

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I and Group III lacks novelty under PCT Article 33(2) as being anticipated by Gilbert et al (*Nature Biotechnology, Volume 15 November 1997, p. 1280-1284*).

Gilbert et al discloses a recombinant protein that carry a string of up to 15 defined cytotoxic T lymphocyte (CTL) epitopes from *Plasmodium falciparum*. Gilbert et al also teach that the recombinant protein have been shown to generate CTL responses in mice when injected via several different routes without adjuvant (see entire article).

Group I is the main invention in this application and it lacks novelty, therefore the other claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

3. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
October 3, 2001

  
MARK NAVARRO  
PRIMARY EXAMINER